UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,983	06/26/2001	Dinesh O. Shah	6821.US.01	9651

23492 7590 10/17/2003

STEVEN F. WEINSTOCK
ABBOTT LABORATORIES
100 ABBOTT PARK ROAD
DEPT. 377/AP6A
ABBOTT PARK, IL 60064-6008

EXAMINER
WORTMAN, DONNA C

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/17/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/891,983	SHAH ET AL.	
	Examin r	Art Unit	
	Donna C. Wortman, Ph.D.	1648	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13-15 and 18-21* is/are pending in the application.

4a) Of the above claim(s) *18-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-11,13-15 and 18-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *26* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claim 12 was canceled and claims 1, 8, and 14 were amended in Paper No. 24 filed 25 July 2003. Claims 1-11 and 13-15 are under examination.

Claims 18-21 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15.

Rejection maintained

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is evident that monoclonal antibodies 107-35-54, 110-81-17, 13-975-157, 14-1350-210, C11-3, C11-7, C11-10, and C11-14 are all required in order to practice the claimed invention since each is specifically recited. Applicant must either comply with the biological deposit rules as set out in 37 CFR 1.801 - 1.809 or demonstrate that each antibody is well-known and readily available to the public. Every member of a Markush group must be enabled.

Applicant has previously established that antibodies C11-3, C11-7, C11-10 and C11-14 are known and available. Applicant has stated that the deposit of hybridoma cell line 107-35-53 (*sic*; 107-35-54?) is described in col. 2, lines 54-55; deposit of cell

line 110-81-17 is described in col. 2, lines 52-53; deposit of cell line 13-975-157 is described in col. 2, lines 61-62; and deposit of cell line 14-1350-210 is described in line 2, lines 64-66 of US Pat No. 5,753,430.

Applicant's remarks have been considered and found partially persuasive. Hybridoma cell line 13-975-157 is clearly identified at lines 60-61 of col. 2 of the patent. Cell line 14-1350-210 is identified at lines 64-66 of the patent. However, since no basis for cell lines named 107-35-54 or 110-81-17 can be located in US Pat. No. 5,753,430, and since no relevant deposit information is contained in the instant specification, one of skill in the art would not know how to practice the invention as claimed using monoclonal antibodies produced by cell lines 107-35-54 and110-81-17.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

<u>New rejection under 35 U.S.C. 102(b)</u>

Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/07023, cited on PTO 892, attached. WO 00/07023 was published 2/2000. US

Patent No. 6,623,921, issued 9/2003, also cited on PTO 892, is the English language equivalent of WO 00/07023 and is relied on for the particulars of this rejection. WO 00/07023 teaches a simultaneous assay for HCV core antigen and HCV antibodies using an antigen that includes core epitopes that do not bind the antibodies used to detect HCV core antigen, where the antigen and antibodies are immobilized on the same solid phase, and where the monoclonal antibodies include C11-14, C11-10, C11-3 and C11-7. See Example 3, Table 1, and Example 6 (US 6,623,921, col. 12 and cols. 16-18, e.g.).

Rejections maintained under 35 USC 102(e)

Claims 1, 2, 4, 13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Publication No. 2002/0192639 A1, Chien et al., of record. Chien et al. disclose kits comprising an HCV antigen and an HCV antibody coated on a single solid phase and conjugates comprising a signal-generating compound, anticipating the claimed subject matter, and a method of detecting HCV antibodies and antigen. See, e.g., the Abstract and Fig. 2.

Claims 1, 2, 4-6, 13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Publication No. 2003/0049608 A1, Bahl et al., of record. Bahl et al. disclose kits comprising an HCV core antigen and an HCV anti-core antibody coated on a single solid phase and conjugates comprising a signal-generating compound, anticipating the claimed subject matter. See, e.g., the Examples and claim 6.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

New rejection under 35 USC 102(b)/103(a)

Claims 13 and 14 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 00/07023. The composition of WO 00/07023 comprising a container containing an HCV antigen and an HCV antibody coated on a solid phase and a conjugate comprising a signal-generating compound is believed to anticipate the subject matter of claims 13 and 14 although it is not explicitly referred to as a "kit" but if not, it would have been obvious to package the composition in the form of a kit as is conventionally done for reasons of convenience and economy.

New rejection under 35 USC 103(a)

Claims 7, 8-11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/07023 as cited above. WO 00/07023 discloses a composition and method for simultaneously detecting the presence of at least one HCV antigen and at least one HCV antibody using at least one HCV antigen and at least one HCV antibody, which may be C11-3, C11-7, C11-10, and/or C11-14, coated on a single solid phase, and using conjugates comprising antibodies attached to the same signal generating compound and detecting the generated signal. The method of WO 00/07023 differs from the claimed method only by exemplifying the use of an enzyme label in place of a chemiluminescent label such as acridinium and by not exemplifying use of a microparticle as a solid phase. It would have been obvious to one of ordinary skill in the art, based on the teachings of WO 00/07023, to have used a chemiluminescent label because WO 00/07023 teaches that any conventional label may be used. It would also have been obvious to use a microparticle as a solid phase for immobilizing the antigen and antibody because WO 00/07023 teaches that any immunoassay solid phase carrier may be used.

Rejections maintained

Claims 7-11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chien et al. as cited above. Chien discloses a method for simultaneously detecting the presence of at least one HCV antigen and at least one HCV antibody using at least one HCV antigen and at least one HCV anti-core antibody, coated on a single solid phase, and using conjugates comprising antibodies attached to the same signal

generating compound and detecting the generated signal. Chien specifically lists suitable labels, including chemiluminescers such as dimethyl acridinium ester (see, e.g., page 8, [0075], as well as suitable solid phases, including beads and particles [0025]. It would have been obvious to one of ordinary skill in the art, based on the teachings of Chien, to have detected both HCV antigen and antibody simultaneously, using a single solid phase coated with HCV antibody and HCV antigen and antibody-chemiluminescent compound conjugates to generate a detectable signal, because Chien exemplifies an assay using the same format as claimed and suggests the use of a chemiluminescent label. It would have been obvious based on the teachings of Chien to have used a microparticle as a solid phase for immobilizing antigens and antibodies because Chien teaches that any conventional immunoassay solid phase may be used for that purpose.

Claims 8-12, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bahl et al., in view of Chien et al., both cited above. Bahl teaches a combination HCV core antigen and antibody assay and teaches that HCV core antigen and HCV antibodies of different types may be detected either together or separately (see, e.g., [0011] and Examples. Bahl further teaches that anti-core monoclonal antibodies C11-3 and C11-7 may be used. The method of Bahl differs from the claimed method only by exemplifying the use of an enzyme label in place of a chemiluminescent label such as acridinium. Chien et al. teaches that any conventional label, including acridinium, can be used in an HCV antigen-antibody combination assay. It would have been obvious to one of ordinary skill in the art to have substituted a chemiluminescent

label as taught by Chien for the exemplified enzyme of Bahl et al. because Bahl et al. requires only a "detectable label" (see, e.g., Bahl et al., claim 8) and because Chien teaches that any conventional label, including a chemiluminescent label, can be used in an HCV antigen-antibody combination assay.

Applicant's response

With respect to the rejections of record based on references available under 35 USC 102(e), Applicant has argued the claimed invention was conceived of and reduced to practice prior to June 14, 2001, which is said to be the filing date of the Chien et al. patent publication, and was conceived of and reduced to practice prior to March 28, 2002, which is said to be the filing date of the Bahl et al. patent publication, and has submitted a Declaration under 37 CFR 1.131 signed by inventors Dawson and Jiang for the purpose of antedating the Chien et al. and the Bahl et al. references.

The Declaration filed on 25 July 2003 under 37 CFR 1.131 has been considered but is ineffective to overcome the Chien et al. and the Bahl et al. references for these reasons:

(1) The Declaration is signed by only two of the coinventors of the rejected claims but the Declaration itself indicates that the Declarants invented the rejected subject matter "along with ... coinventors." All of the inventors of the rejected claims must sign a Declaration under 35 CRF 1.131 (please see MPEP 715).

(2) The Declaration does not state that the invention was made in the United States or a NAFTA country or a WTO member country (see MPEP 715).

(3) The Declaration is insufficient to antedate the Chien et al. and the Bahl et al. references, because the Declaration states that the invention of the relevant claims was completed before 14 June 2001; however, the Chien et al. reference has the benefit of priority of provisional application 60/212082, which was filed 15 June 2000, and the Bahl et al. reference receives the benefit of priority of provisional application 60/279276, which was filed 28 March 2001.

Rejections withdrawn

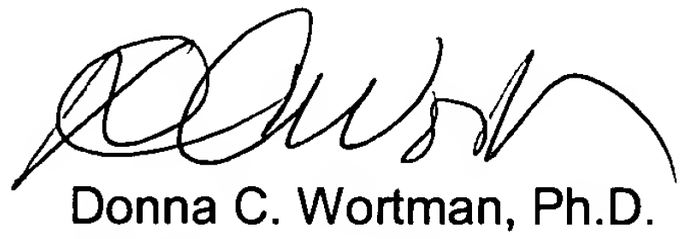
On further consideration, the rejections over Aoyagi et al., US Patent Publication No. 2002/0173493 A1, available under 35 USC 102(e), have been withdrawn in favor of rejections formulated under 35 USC 102(b) over WO 00/07023 as set forth above.

The rejection of claims 12, 14, and 15 under 35 USC 103(a) over Dawson in view of Masalova et al. is withdrawn in view of the cancelation of claim 12 and the amendment of claim 14 to depend only from claim 13.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw